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10/511,018	03/14/2005	Tetsuo Santo	JCLA14660	8744

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J C PATENTS, INC.
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IRVINE, CA 92618

EXAMINER

CLARK, AMY LYNN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,018

Applicant(s)

SANTO ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 8 September 2006 with the amendment of Claims 1-12.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 are currently pending.

Claims 1-12 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 2 recites the limitation "said extracts drawn from plants" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Drawings

The drawings remain objected to because the images are still unclear due to the fact that the photographs are dark and appear to have large, black dots scattered in

rows all over the photographs, therefore, it is difficult to see what Applicant is trying to illustrate via the photographs. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 8 September 2006, with respect to the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Noevir (U*), of claim 1 under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (V*) and of claim 1 under 35 U.S.C. 102(b) as

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being anticipated by Whittle (A*) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Tze et al. (N, WO 02/067960 A1).

Newly amended Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tze et al. (WO 02/067960 A1). Newly applied as necessitated by amendment.

Tze teaches a composition comprising herbs, such as *Isatis tinctoria* and *Sophora flavescens* (See page 8, lines 18, 19, 21-23, 25 and 28 and page 9, lines 25 and 27), in the form of a paste (See page 13, lines 10-13).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ

430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 8 September 2006, with respect to the rejection(s) of claim(s) 1-8 under 35 U.S.C. 103(a) as being unpatentable over Whittle (A*), in view of Yoshioka et al. (B*) and with respect to the rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Whittle (A*), in view of Yoshioka et al. (B*), Noevir (U*), Nakayama et al. (C*), Ishikawa et al. (D*), Huang et al. (E*), Grollier et al. (F*) and Liang et al. (G*) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tze (N, WO 02/067960 A1), in view of http://web.archive.org/web/*/http://holistic-online.com/Herbal-Med/Herbs/h358.htm (W), Whittle (A*), Huang et al. (B*), Yoshioka et al. (C*), Noevir (U*), Nakayama et al. (D*), Ishikawa et al. (E*), Huang et al. (F*), Grollier et al. (G*) and Liang et al. (H*).

Newly amended claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tze (N, WO 02/067960 A1), in view of http://web.archive.org/web/*/http://holistic-online.com/Herbal-Med/Herbs/h358.htm (V), Whittle (A*), Huang et al. (B*), Yoshioka et al. (C*), Noevir (U*), Nakayama et al. (D*),

Ishikawa et al. (E*), Huang et al. (F*), Grollier et al. (G*) and Liang et al. (H*). Newly applied as necessitated by amendment.

Tze teaches a composition comprising herbs, such as *Isatis tinctoria* (which is commonly used to treat psoriasis, as taught by

http://web.archive.org/web/*/http://holistic-online.com/Herbal-Med/Herbs/h358.htm)

and *Sophora flavescens* (See page 8, lines 18, 19, 21-23, 25 and 28 and page 9, lines 25 and 27), as chemopreventive and therapeutic agents (See page 1, lines 5 and 6) in the form of a paste (See page 13, lines 10-13), which may be applied topically.

Whittle teaches a composition for topical administration in the form of a cream for treating skin disorders such as eczema and psoriasis (See Abstract and column 3, lines 63-65) comprising of alcohol extracts of licorice, lightyellow sophora root, moutan bark and Baikal skullcap (See column 3, lines 24-33 and 54-62 and columns 9 and 11).

Whittle further teaches a composition for topical administration comprising of white soft paraffin (See column 7, Example 8).

Huang teaches a composition for treating psoriasis in the form of a topical dosage, such as a cream or soft gel (See abstract) comprising radix angelicae sinensis, which is synonymous with *Angelicae sinensis* (Oliv.) Diels, and *Isatis indigotica*, which is synonymous with *Istatis tinctoria*.

Yoshioka teaches a composition in the form of a microcapsule comprising of mutton oil (See column 13, lines 23 and 34), salicylic acid, glycyrrhiza extract (please note that glycyrrhiza is synonymous with licorice), Japanese angelica root extract and lemon extract (See column 15, lines 35 and 40-56), which may be applied to the skin in

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the form of a cream (See column 70, Example 48) or in the form of a lotion (See column 66, Example 44). Yoshioka further teaches that each of these components are present in an amount of 0.01 to 99% by weight.

Noevir teaches a skin cleansing cream for preventing rough skin comprising of extracts of turmeric and magnolia bark. Noevir further teaches a skin cleansing cream for preventing rough skin further comprising of extracts of cnidii rhizome (which is synonymous with cnidii rhizome) and Angelica radix (which is synonymous with Japanese Angelica).

Nakayama teaches a skin care composition comprising of glycyrrhiza extract, resorcinol (See page 1, paragraph 0009) and its derivatives in an amount of 0.0001 to 20 w/w% (See page 9, paragraphs 0143-0145), Japanese angelica extract in an amount of 0.001 to 20 w/w % (See page 2, paragraphs 0013 and 0014), salicylic acid in an amount of 0.0001-5 w/w % (See page 2, paragraphs 0015 and 0016), and angelica dahurica root in an amount of 0.001 to 5 w/w % (See page 3, paragraphs 0045 and 0046), which can be applied in the form of a cream (See page 10, paragraph 0155). Please note that Nakayama does not expressly teach that the composition can be used to treat dermatitis, however, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (See also MPEP § 2112 - § 2112.02).

Ishikawa teaches a cosmetic moisturizer (See Abstract) for preventing and remedying skin roughness (See page 4, paragraphs 0046 and 0048), which is a

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symptom of dermatitis, in the form of a cream (See page 7, paragraph 0087) comprising of salicylic acid in an amount of 0.0001 to 5% by weight (See page 4, paragraph 0045), Amur cork tree, licorice, Cnidii rhizome and lemon all in an amount of 0.000001 to 20% by weight (See page 4, paragraphs 0047 and 0048).

Grollier teaches a cosmetic composition for treating skin (See Abstract) in the form of a cream (See column 6, lines 58-64) comprising of water pepper (*Polygonum hydropiper*) (See column 4, lines 22-23), which is synonymous with smartweed, in an amount of 5 to 30 weight % (See column 4, lines 62-68) and sheep oil (which reads on mutton oil) (See column 5, lines 24-27).

Laing teaches a composition in the form of a cream (See page 3, paragraph 0040) suppository for treating human ailments (See Abstract and page 1 paragraph 0013 continued onto page 2) comprising of *Dryobalanops Aromatica* (which is synonymous with Borneo Camphor tree) and *Angelica Dahurica* in an amount of 1 % to 2% of the total weight of the composition (See page 3, paragraphs 0044 and 0045 and page 1 paragraph 0013 continued onto page 2), which read on the percentages of Borneo Camphor tree and *Angelica Dahurica* as claimed by Applicant. Please note that Laing does not expressly teach that the composition can be used to treat dermatitis, however, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (See also MPEP § 2112 - § 2112.02).

The teachings of Tze, http://web.archive.org/web/*/http://holistic-online.com/Herbal-Med/Herbs/h358.htm, Whittle, Huang, Yoshioka, Noevir,

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Nakayama, Ishikawa, Huang, Grollier and Liang are set forth above. Tze does not expressly teach a cream for therapy of dermatitis comprising an auxiliary agent, Baikal Skullcap, Amur cork tree, Angelicae Dahuricae root, lemon, licorice, smartweed, cnidii rhizome, Japanese Angelica root, mutton oil, salicylic acid and resorcinol, turmeric, magnolia bark, isatis leaf, and borneo camphor tree, nor does Tze teach the specific amounts of each component in a volume ratio. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Tze to make a skin care composition for treating dermatitis with a composition comprising of lightyellow sophora root, turmeric, magnolia bark, moutan bark, Isatis leaf, Borneo Camphor tree, Baikal skullcap, Amur cork tree, Angelicae Dahuricae root, lemon, smartweed, licorice, cnidii rhizome, Japanese Angelica Root, salicylic acid, resorcinol, mutton oil, alcohol and white soft paraffin because at the time the invention was made, the beneficial effects of a composition in the form of a paste comprising Lightyellow sophora root and Isatis leaf were known, as clearly taught by Tze, as was that Isatis leaf is used to treat psoriasis, as clearly taught by http://web.archive.org/web/*/http://holistic-online.com/Herbal-Med/Herbs/h358.htm, as were the beneficial effects of a topical composition comprising licorice, lightyellow sophora root, moutan bark, Baikal skullcap and white soft paraffin, as clearly taught by Whittle, as a topical composition comprising of licorice, lightyellow sophora root, moutan bark, Baikal skullcap and white soft paraffin for treating skin disorders was known, as clearly taught by Whittle, as were the beneficial effects of mutton oil, salicylic acid,

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licorice, Japanese angelica root extract and lemon extract and the combination of mutton oil, salicylic acid, licorice, Japanese angelica root extract and lemon extract composition to make a cream for application to skin, as clearly taught by Yoshioka, as were the beneficial effects of turmeric, magnolia bark, cnidii rhizome and *Angelica radix* for preventing rough skin, as clearly taught by Noevir, as were the beneficial effects of glycyrrhiza extract, resorcinol, Japanese angelica extract, salicylic acid, and angelica dahurica root and the application of the composition to the skin, as taught by Nakayama, as were the beneficial effects of Amur cork tree, licorice, *Cnidii rhizome*, lemon and salicylic acid and a cosmetic moisturizer for preventing and remedying skin roughness, which is a symptom of dermatitis, comprising a composition of Amur cork tree, licorice, *Cnidii rhizome*, lemon and salicylic acid, as taught by Ishikawa, as were the beneficial effects of isatis leaf for treating psoriasis, which is a type of dermatitis, as clearly taught by Huang, as were the beneficial effects of a composition for treating skin comprising of smartweed and mutton oil, as clearly taught by Grollier, as were the beneficial effects of Borneo Camphor tree and *Angelica Dahurica*, as clearly taught by Laing. It would have also been obvious to one of ordinary skill in the art to adjust the amounts of the extracts of lightyellow sophora root, turmeric, lemon extract, turmeric, magnolia bark, moutan bark, isatis leaf, borneo camphor tree, Baikal skullcap, Amur cork tree, *Angelicae Dahuricae* root, lemon, smartweed, *cnidii rhizome*, Japanese *Angelica* root, mutton oil, salicylic acid and resorcinol, as taught Whittle, Yoshioka, Noevir, Nakayama, Ishikawa, Huang, Grollier and Liang to provide the instantly claimed invention at the time the invention was made.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

The teachings of Whittle and Yoshioka are set forth above. Whittle does not expressly teach a cream for therapy of dermatitis comprising of mutton oil, salicylic acid, nor does Whittle teach that the ratios of the extracts drawn from plants: accelerating agent for skin permeation: accelerating agent for keratinization in said auxiliary agent are 53 to 89%: 8 to 38%: 6 to 10%". However, at the time the invention was made, it

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would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Whittle to make a skin care composition for treating dermatitis with a composition comprising of mutton oil, salicylic acid, licorice, Japanese angelica root, lemon extract, lightyellow sophora root, moutan bark and Baikal skullcap because at the time the invention was made, the beneficial effects of licorice, lightyellow sophora root, moutan bark, Baikal skullcap and white soft paraffin and a topical composition comprising of licorice, lightyellow sophora root, moutan bark, Baikal skullcap and white soft paraffin for treating skin disorders was known, as clearly taught by Whittle, as were the beneficial effects of mutton oil, salicylic acid, licorice, Japanese angelica root extract and lemon extract and the combination of mutton oil, salicylic acid, licorice, Japanese angelica root extract and lemon extract composition to make a cream for application to skin, as clearly taught by Yoshioka. It would have also been obvious to one of ordinary skill in the art to adjust the amounts of the extracts of lemon extract, lightyellow sophora root, moutan bark and Baikal skullcap, the amount of the accelerating agent for skin permeation (Japanese Angelicae root) and the amount of accelerating agent for keratinization (salicylic acid) to provide the ratios of the extracts drawn from plants: accelerating agent for skin permeation: accelerating agent for keratinization as 53 to 89%: 8 to 38%: 6 to 10%, as taught by both Whittle and Yoshioka to provide the instantly claimed invention at the time the invention was made.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed

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composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
November 14, 2006


MICHELE FLOOD
PRIMARY EXAMINER